



Information for the patient Alynni 150 mg hard capsules alectinib

This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start taking this medicine – because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Alynni is and what it is used for
2. What you need to know before you take Alynni
3. How to take Alynni
4. Possible side effects
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6. Contents of the pack and other information

1. What Alynni is and what it is used for

What Alynni is

Alynni is a cancer medicine that contains the active substance alectinib.

What Alynni is used for

Alynni is used to treat adults with a type of lung cancer called 'non-small cell lung cancer' (NSCLC). It is used if your lung cancer:

- is 'ALK-positive' - this means your cancer cells have a fault in a gene that makes an enzyme called ALK (anaplastic lymphoma kinase), see 'How Alynni works', below
- and is advanced
- and has previously been treated with a medicine called 'crizotinib'.

How Alynni works

Alynni blocks the action of an enzyme called 'ALK tyrosine kinase'. Abnormal forms of this enzyme (due to fault in the gene that makes it) help encourage cancer cell growth. Alynni may slow down or stop the growth of your cancer. It may also help to shrink your cancer.

If you have any questions about how Alynni works or why this medicine has been prescribed for you, ask your doctor, pharmacist or nurse.

2. What you need to know before you take Alynni

Do not take Alynni:

- if you are allergic to alectinib or any of the other ingredients of this medicine (listed in section 6).
- If you are not sure, talk to your doctor, pharmacist or nurse before taking Alynni.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Alynni:

- if you have an inherited problem called 'galactose intolerance', 'congenital lactase deficiency' or 'glucose-galactose malabsorption'.
- If you are not sure, talk to your doctor, pharmacist or nurse before taking Alynni.

Alynni can cause side effects that you need to tell your doctor about straight away. These include:

- liver injury (hepatotoxicity). Your doctor will take blood tests before you start treatment, then every 2 weeks for the first 3 months of your

- Do not breast-feed while taking this medicine. This is because it is not known if Alynni can pass over into breast milk and could therefore harm your baby.

Driving and using machines

Take special care when driving and using machines as you may develop problems with vision or slowing of the heart/beat or low blood pressure that can lead to fainting or dizziness while you are taking Alynni.

Alynni contains lactose

Alynni contains lactose (a type of sugar). If you have been told by your doctor that you cannot tolerate or digest some sugars, talk to your doctor before taking this medicine.

Alynni contains sodium

The recommended daily dose of Alynni (1200 mg) contains 48 mg of sodium. Please take this amount into consideration if you are on a controlled sodium diet.

3. How to take Alynni

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor, pharmacist or nurse if you are not sure.

How much to take

- The recommended dose is 4 capsules (600 mg) twice a day.
- This means you take a total of 8 capsules (1200 mg) each day.
- Sometimes your doctor may lower your dose, stop your treatment for a short time or stop your treatment completely if you feel unwell.

How to take

- Alynni is taken by mouth. Swallow each capsule whole. Do not open or dissolve the capsules.
- You must take Alynni with food.

If you vomit after taking Alynni

If you vomit after taking a dose of Alynni, do not take an extra dose, just take your next dose at the usual time.

If you take more Alynni than you should

If you take more Alynni than you should, talk to a doctor or go to hospital straight away. Take the medicine pack and this leaflet with you.

If you forget to take Alynni

- If it is more than 6 hours until your next dose, take the missed dose as soon as you remember.
- If it is less than 6 hours until your next dose, skip the missed dose. Then take your next dose at the usual time.
- Do not take a double dose to make up for a missed dose.

If you stop taking Alynni

Do not stop taking this medicine without talking to your doctor first. It is important to take Alynni twice a day for as long as your doctor prescribes it for you.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. The following side effects may happen with this medicine.

Some side effects could be serious.

Tell your doctor straight away if you notice any of the following side effects. Your doctor may lower your dose, stop your treatment for a short time or stop your treatment completely:

- Yellowing of your skin or the whites of your eyes, pain on the right side of your stomach area, dark urine, itchy skin, feeling less hungry than usual, nausea or vomiting, feeling tired, bleeding or bruising more easily than normal (potential signs of liver problems)
- New or worsening signs of muscle problems, including unexplained muscle pain or muscle pain that does not go away, tenderness, or weakness (potential signs of muscle problems).
- Fainting, dizziness and low blood pressure (potential signs of slow heart beat)
- New or worsening signs including difficulty in breathing, shortness of breath, or cough with or without mucus, or fever - the signs may be similar to those from your lung cancer (potential signs of lung inflammation – pneumonitis). Alynni can cause severe or life-threatening inflammation of the lungs during treatment.

Other side effects

Tell your doctor, pharmacist or nurse if you notice any of the following side effects:

Very common (may affect more than 1 in 10 people):

- abnormal results of blood tests to check for liver problems (high levels of alanine aminotransferase, aspartate aminotransferase and bilirubin).

treatment and then less often. This is to check you do not have any liver problems while taking Alynni. Tell your doctor straight away if you get any of the following signs: yellowing of your skin or the whites of your eyes, pain on the right side of your stomach area, dark urine, itchy skin, feeling less hungry than usual, nausea or vomiting, feeling tired, bleeding or bruising more easily than normal.

- slow heart beat (bradycardia).
- lung inflammation (pneumonitis). Alynni may cause severe or life-threatening swelling (inflammation) of the lungs during treatment. The signs may be similar to those from your lung cancer. Tell your doctor straight away if you have any new or worsening signs including difficulty in breathing, shortness of breath, or cough with or without mucus, or fever.
- Severe muscle pain, tenderness, and weakness (myalgia). Your doctor will do blood tests at least every 2 weeks for the first month and as needed during treatment with Alynni. Tell your doctor straight away if you get new or worsening signs of muscle problems, including unexplained muscle pain or muscle pain that does not go away, tenderness, or weakness.

Look out for these while you are taking Alynni. See 'Side effects' in section 4 for more information.

Sensitivity to sunlight

Do not expose yourself to the sun for any long period of time while you are taking Alynni and for 7 days after you stop. You need to apply sunscreen and lip balm with a Sun Protection Factor of 50 or higher to help prevent sunburn.

Children and adolescents

Alynni has not been studied in children or adolescents. Do not give this medicine to children or adolescents under the age of 18 years.

Tests and checks

When you take Alynni your doctor will do blood tests before you start treatment, then every 2 weeks for the first 3 months of your treatment and then less often. This is to check you do not have any liver or muscle problems while taking Alynni.

Other medicines and Alynni

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

This includes medicines obtained without a prescription, and herbal medicines. This is because Alynni can affect the way some other medicines work. Also some other medicines can affect the way Alynni works.

In particular tell your doctor or pharmacist if you are taking any of the following medicines:

- digoxin, a medicine used to treat heart problems
- dabigatran etexilate, a medicine used to treat blood clots
- methotrexate, a medicine used to treat certain types of cancer or to treat autoimmune diseases (e.g. rheumatoid arthritis)
- nilotinib, a medicine used to treat certain types of cancer
- lapatinib, a medicine used to treat certain types of breast cancer
- mitoxantrone, a medicine used to treat certain types of cancer or autoimmune diseases (e.g. multiple sclerosis)
- everolimus, a medicine used to treat certain types of cancer or used to prevent the body's immune system from rejecting a transplanted kidney, heart or liver.
- sirolimus, a medicine used to prevent the body's immune system from rejecting a transplanted kidney, heart or liver.
- toptotecan, a medicine used to treat certain types of cancer
- medicines used to treat AIDS/HIV (e.g. ritonavir, saquinavir)
- medicines used to treat infections. These include medicines that treat fungal infections (antifungals such as ketoconazole, itraconazole, voriconazole, posaconazole) and medicines that treat certain types of bacterial infection (antibiotics such as telithromycin)
- St. John's Wort, a herbal medicine used to treat depression
- medicines used to stop seizures or fits (anti-epileptics such as phenytoin, carbamazepine, or phenobarbital)
- medicines used to treat tuberculosis (e.g. rifampicin, rifabutin)
- nefazodone, a medicine used to treat depression

Oral contraceptives

If you take Alynni whilst using oral contraceptives, the oral contraceptives may be less effective.

Alynni with food and drink

You should use caution when drinking grapefruit juice or eating grapefruit or Seville oranges while on treatment with Alynni as they may change the amount of Alynni in your body.

Contraception, pregnancy, and breast-feeding - information for women

Contraception – information for women

● You should not become pregnant while taking this medicine. If you are able to become pregnant, you must use highly effective contraception while on treatment and for at least 3 months after stopping treatment. Talk to your doctor about the right methods of contraception for you and your partner. If you take Alynni whilst using oral contraceptives, the oral contraceptives may be less effective.

Pregnancy

- Do not take Alynni if you are pregnant. This is because it may harm your baby.
- If you become pregnant when taking the medicine or during the 3 months after taking your last dose, tell your doctor straight away.

Breast-feeding

- you may feel tired, weak or short of breath due to a reduction in the number of red blood cells, known as anaemia
- blurred vision, loss of sight, black dots or white spots in your vision, and seeing double (problems with your eyes)
- vomiting – if you vomit after taking a dose of Alynni, do not take an extra dose, just take your next dose at the usual time
- constipation
- diarrhoea
- nausea
- rash
- sensitivity to sunlight – do not expose yourself to the sun for any long period of time while you are taking Alynni and for 7 days after you stop. You need to apply sunscreen and lip balm with a Sun Protection Factor of 50 or higher to help prevent sunburn.
- swelling caused by fluid build-up in the body (oedema).

Common (may affect up to 1 in 10 people):

- abnormal results of blood tests to check kidney function (high level of creatinine).

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Alynni

- Keep this medicine out of the sight and reach of children.
- Do not take this medicine after the expiry date which is stated on the carton and the blister or the bottle after EXP.
- Store in the original package in order to protect from moisture.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Alynni contains

- The active substance is alectinib. Each hard capsule contains alectinib hydrochloride equivalent to 150 mg alectinib.
- The other ingredients are:
- Capsule content: lactose monohydrate, hydroxypropylcellulose, sodium laurilsulfate, magnesium stearate and carmellose calcium
- Capsule shell: hypromellose, carageenan, potassium chloride, titanium dioxide, maize starch and carnauba wax

The capsules are provided in blisters or in bottle, are available in cartons containing 56 hard capsules. Not all pack size may be marketed.

Marketing Authorisation Holder

Tongmeng(Lao) Pharmaceutical and Food Co., Ltd
Rd13 South,31km,Ban Naphasuk,Sathany District
Ventiane
Lao PDR

Manufacturer

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For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder.



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